



AUG 25 2008

K072098

SonoSite, Inc.
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Bothell, WA 98021-3904 USA

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510(K) Summary of Safety and Effectiveness

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

SonoSite, Inc., 21919 30th Drive SE, Bothell, WA 98021-3904 USA

Corresponding Official: Christopher J. Hartzog, Sr. Regulatory Affairs Specialist
E-mail: chris.hartzog@sonosite.com
Telephone: (425) 951-1419
Facsimile: (425) 951-1201
Date prepared: July 1, 2008

2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/ Usual Name

Diagnostic Ultrasound System with Accessories

Proprietary Name

SonoSite Maxx™ Series Ultrasound System (*subject to change*)

Classification Names

Name	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX
Picture Archiving And Communications System	892.2050	90-LLZ

3) Identification of the predicate or legally marketed device:

SonoSite, Inc. believes that the System described in this Submission is substantially equivalent to a combination of the SonoSite Maxx™ Series Ultrasound System (K071134), the SonoSite MicroMaxx® Ultrasound System (K053069 and K043559), the Philips Medical Systems HDI® 5000 Ultrasound System (K034003 and K011224) and the GE Logiq 9 Ultrasound System (K061129).

4) Device Description:

The SonoSite Maxx Series Ultrasound System is a full featured, general purpose, software controlled, diagnostic ultrasound system used to acquire and display high-resolution, real-time ultrasound data in 2D, 2D Chroma, THI, M-Mode, Pulsed Wave (PW) Doppler, Continuous Wave (CW) Doppler, Color Power Doppler, Velocity Color Doppler, Anatomical M-Mode, Color M-Mode, Pulsed Wave Tissue Doppler Imaging (PW-TDI), Color Tissue Doppler Imaging (Color-TDI), Elastography (Strain), Strain Rate Imaging, tissue 3D, tissue 4D and flow 3D imaging or in a combination of these modes. The SonoSite Maxx Series is a design that readily lends itself to be configured to specific ultrasound imaging applications through physical packaging adaptations and system feature selections.

5) Indications for Use

The device is intended for prescription use (Per 21 CFR 801.109) for diagnostic ultrasound imaging or fluid flow analysis of the human body in the following clinical applications:

Ophthalmic	Adult Cephalic
Fetal - OB/GYN	Trans-rectal
Abdominal	Trans-vaginal
Intra-operative (Abdominal organs and vascular)	Musculo-skel. (Conventional)
Intra-operative (Neuro.)	Musculo-skel. (Superficial)
Laparoscopic	Cardiac Adult
Pediatric	Cardiac Pediatric
Small Organ (breast, thyroid, testicles, prostate)	Trans-esophageal (card.)
Neonatal Cephalic	Peripheral vessel

5) Comparison with Predicate Devices

The SonoSite Maxx™ Series Ultrasound System is of a comparable type and substantially equivalent to the current SonoSite Maxx™ Series Ultrasound System. It has the same technological characteristics, safety and effectiveness features, the same physical design and materials. The system has the same intended use and basic operating modes as the SonoSite, Philips HDI5000 and GE Logiq 9 predicate devices.

6) Performance Data

The device is verified and validated according to the company's design control process.

7) Conclusion

Intended uses and other key features are consistent with traditional clinical practice and FDA guidance. The product development process conforms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable electromedical device safety standards with compliance verified through independent evaluation and ongoing factory audits. Medical diagnostic ultrasound has an established history of safety and effectiveness. It is the opinion of SonoSite, Inc. that the SonoSite Maxx™ Series Ultrasound System is substantially equivalent with regard to safety and effectiveness to other devices already cleared for marketing.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2008

SonoSite, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K082098
Trade/Device Name: SonoSite Maxx™ Series Ultrasound System (SiteLink™ Image Manager and SonoSite® DICOM/Clips Bundle)
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX, and LLZ
Dated: July 24, 2008
Received: July 25, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SonoSite Maxx™ Series Ultrasound System (SiteLink™ Image Manager and SonoSite® DICOM/Clips Bundle), as described in your premarket notification:

Transducer Model Number

BPTRTx/8-5
C8x/8-5
C11x/8-5
D2x/2

D5x/5
C60x/5-2
HFL38x/13-6
HFL50x/15-6

ICTx/8-5
L25x-13-6
L38x/10-5
L52x/10-5

LAPx/12-5
MiniTEEx/7-3
P10x/8-4
P17x/5-1
P21x/5-1
SLAx/13-6
SLTx/10-5

TCDx/2
TEEx/8-3
L25Bx/10-5
LFL38x/7-3
P21Dx/5-1
P21MCx/5-1
P21Sx/7-1

WC40x/6-2
WC60x/6-2
WL25x/12-5
WL40x/12-5
WMC15x/12-4
WMC20x/12-4
WTVx/9-3

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled,

"Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Andrew Kang, M.D. at (240) 276-3666.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

K082098

Table 4.3- 1 Diagnostic Ultrasound Indications for Use Form – SonoSite Maxx™ Series Ultrasound System

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	N/A						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P	P		P	B+M; B+PWD; B+CD	
Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Laparoscopic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-rectal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-vaginal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-esophageal (card.)	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, and imaging for guidance of biopsy. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. Includes imaging to assist in the placement of needles and catheters in vascular or other anatomical structures and imaging guidance for peripheral nerve block procedures. Includes imaging of spinal cord to provide guidance for central nerve block procedures. Includes picture archiving, communications and storage functionality. M-Mode includes anatomical M-Mode, and color M-Mode. System includes wireless voice activated remote control capabilities. System includes the ability to perform measurements on recalled images.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

510(k) Number

K082098

Indications for Use

Section 4.3

INDICATIONS FOR USE

510(k) Number (if known): K082098

Device Name: SiteLink™ Image Manager

Indications for Use: SiteLink™ Image Manager is a software accessory for SonoSite Maxx Series medical diagnostic ultrasound systems. SiteLink enables image download, in full resolution .bmp format or compressed .jpg format, from SonoSite systems to a Windows-based PC.

Prescription Use:



or

Over-The-Counter Use:



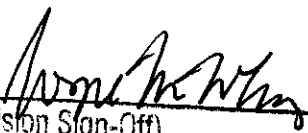
(Part 21 CFR 801 Subpart D)

(Part 21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)


(Division Sign-Off)
ion of Reproductive, Abdominal and
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510(k) Number K082098

INDICATIONS FOR USE

510(k) Number (if known): K082098

Device Name: SonoSite® DICOM/Clips Bundle

Indications for Use: The SonoSite® DICOM/Clips Bundle is a software option available on SonoSite Maxx Series™ medical diagnostic ultrasound systems. It is intended for acceptance, transfer, display, storage, archive and manipulation of digital medical images, including quantification and report generation.

Prescription Use:



or

Over-The-Counter Use:



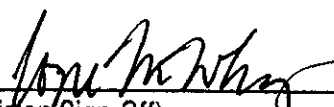
(Part 21 CFR 801 Subpart D)

(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)



(Division Sign-Off)
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510(k) Number K082098

K082098

Table 4.3- 2 Diagnostic Ultrasound Indications for Use Form – BPTRTx/8-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	BPTRTx/8-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-vaginal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							


N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off,
 Division of Reproductive, Abdominal and
 Biological Devices
 510(k) Number K082098

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Table 4.3- 3 Diagnostic Ultrasound Indications for Use Form – C8x/8-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	C8x/8-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-vaginal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							


N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)


 (Division Sign-Off)
 Division of Reproductive, Abdominal and
 Biological Devices
 (k) Number K082098

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Table 4.3- 4 Diagnostic Ultrasound Indications for Use Form - C11x/8-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	C11x/8-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Laparoscopic							
Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices

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Table 4.3- 5 Diagnostic Ultrasound Indications for Use Form - D2x/2 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	D2x/2 MHz Dual Element Circular Array						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult				P			
Cardiac Pediatric				P			
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

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Table 4.3- 6 Diagnostic Ultrasound Indications for Use Form – D5x/5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	D5x/5 MHz Dual Element Circular Array						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult				P			
Cardiac Pediatric				P			
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
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Table 4.3- 7 Diagnostic Ultrasound Indications for Use Form - C60x/5-2 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	C60x/5-2 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number



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Table 4.3- 8 Diagnostic Ultrasound Indications for Use Form - HFL38x/13-6 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	HFL38x/13-6 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 9 Diagnostic Ultrasound Indications for Use Form – HFL50x/15-6 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	HFL50x/15-6 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 10 Diagnostic Ultrasound Indications for Use Form – ICTx/8-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	ICTx/8-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-vaginal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

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Table 4.3- 11 Diagnostic Ultrasound Indications for Use Form – L25x/13-6 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	L25x/13-6 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N			N	B+M; B+CD	Note 1
Fetal							
Abdominal	P	P			P	B+M; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P			P	B+M; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P			P	B+M; B+CWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P			P	B+M; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P			P	B+M; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P			P	B+M; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P			P	B+M; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

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Table 4.3- 12 Diagnostic Ultrasound Indications for Use Form - L38x/10-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	L38x/10-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode Includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

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Table 4.3- 13 Diagnostic Ultrasound Indications for Use Form – L52x/10-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	L52x/10-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new Indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

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Table 4.3- 14 Diagnostic Ultrasound Indications for Use Form – LAPx/12-5 Laparoscopic Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	LAPx/12-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

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Table 4.3- 15 Diagnostic Ultrasound Indications for Use Form – MiniTEEx/7-3 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	MiniTEEx/7-3 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 16 Diagnostic Ultrasound Indications for Use Form – P10x/8-4 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	P10x/8-4 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Fetal	P	P	P		P	B+M; B+PWD B+CD	Note 1
Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Intra-operative (Neuro.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Neonatal Cephalic	P	P	P		P	B+M; B+PWD B+CD	Note 1
Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 17 Diagnostic Ultrasound Indications for Use Form – P17x/5-1 Transducer

System:	SonoSite Maxx™ Series Ultrasound System							
Transducer:	P17x/5-1 MHz Transducer							
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:							
Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)	
Ophthalmic	P	P	P		P	B+M; B+PWD; B+CD	Note 1	
Fetal	P	P	P		P	B+M; B+PWD B+CD	Note 1	
Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1	
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD B+CD	Note 1	
Intra-operative (Neuro.)								
Laparoscopic								
Pediatric	P	P	P		P	B+M; B+PWD	Note 1	
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD B+CD	Note 1	
Neonatal Cephalic	P	P	P		P	B+M; B+PWD B+CD	Note 1	
Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1	
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph. (non-Card.)								
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD B+CD	Note 1	
Musculo-skel. (Superfic.)								
Intra-luminal								
Other (spec.)								
Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1	
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1	
Trans-esophageal (card.)								
Other (spec.)								
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1	
Other (spec.)								

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 18 Diagnostic Ultrasound Indications for Use Form – P21x/5-1 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	P21x/5-1 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Fetal	P	P	P		P	B+M; B+PWD B+CD	Note 1
Abdominal	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Neonatal Cephalic	P	P	P		P	B+M; B+PWD B+CD	Note 1
Adult Cephalic	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD B+CD	Note 1
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Cardiac Pediatric	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode Includes anatomical M-Mode, and color M-Mode.


All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 19 Diagnostic Ultrasound Indications for Use Form – SLAx/13-6 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	SLAx/13-6 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 20 Diagnostic Ultrasound Indications for Use Form – SLTx/10-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	SLTx/10-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Abdominal	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	P	P	P		P	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 21 Diagnostic Ultrasound Indications for Use Form – TCDx/2 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	TCDx/2 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic			P				
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic			N				
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

All items marked "P" were previously cleared in 510(k) K071134.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 22 Diagnostic Ultrasound Indications for Use Form – TEEEx/8-3 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	TEEx/8-3 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)	P	P	P	P	P	B+M; B+PWD; B+CWD; B+CD	Note 1
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

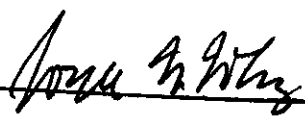
All items marked "P" were previously cleared in 510(k) K071134.

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Table 4.3- 23 Diagnostic Ultrasound Indications for Use Form – L25Bx/10-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	L25Bx/10-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Fetal							
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 24 Diagnostic Ultrasound Indications for Use Form – LFL38x/7-3 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	LFL38x/7-3 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal							
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging of spinal cord to provide guidance for central nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 25 Diagnostic Ultrasound Indications for Use Form – P21Dx/5-1 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	P21Dx/5-1 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Fetal	N	N	N		N	B+M; B+PWD B+CD	Note 1
Abdominal	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD B+CD	Note 1
Neonatal Cephalic	N	N	N		N	B+M; B+PWD B+CD	Note 1
Adult Cephalic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD B+CD	Note 1
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Cardiac Pediatric	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 26 Diagnostic Ultrasound Indications for Use Form – P21MCx/5-1 Transducer


System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	P21MCx/5-1 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Abdominal	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)


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Table 4.3- 27 Diagnostic Ultrasound Indications for Use Form – P21Sx/7-1 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	P21Sx/7-1 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Abdominal	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult	N	N	N	N	N	B+M; B+PWD; B+CWD; B+CD	Note 1
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), color TDI, elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 28 Diagnostic Ultrasound Indications for Use Form – WC40x/6-2 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	WC40x/6-2 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

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Table 4.3- 29 Diagnostic Ultrasound Indications for Use Form – WC60x/6-2 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	WC60x/6-2 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 30 Diagnostic Ultrasound Indications for Use Form – WL25x/12-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	WL25x/12-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Fetal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

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Indications for Use

Section 4.3

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Table 4.3- 31 Diagnostic Ultrasound Indications for Use Form -- WL40x/12-5 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	WL40x/12-5 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Fetal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Abdominal	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-operative (Abdominal organs and vascular)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-operative (Neuro.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Laparoscopic							
Pediatric	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Neonatal Cephalic	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Adult Cephalic							
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Musculo-skel. (Superfic.)	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N		N	B+M; B+PWD; B+CD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

Division of Reproductive, Abdominal and Radiological Devices

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Table 4.3- 32 Diagnostic Ultrasound Indications for Use Form – WMC15x/12-4 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	WMC15x/12-4 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Fetal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Abdominal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Intra-operative (Abdominal organs and vascular)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Intra-operative (Neuro.)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Laparoscopic							
Pediatric	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Neonatal Cephalic	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Adult Cephalic	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Musculo-skel. (Superfic.)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)

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Table 4.3- 33 Diagnostic Ultrasound Indications for Use Form – WMC20x/12-4 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	WMC20x/12-4 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Fetal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Abdominal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Intra-operative (Abdominal organs and vascular)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Intra-operative (Neuro.)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Laparoscopic							
Pediatric	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Small Organ (breast, thyroid, testicles, prostate)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Neonatal Cephalic	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Adult Cephalic	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Trans-rectal							
Trans-vaginal							
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Musculo-skel. (Superfic.)	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging guidance for peripheral nerve block procedures, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

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Table 4.3- 34 Diagnostic Ultrasound Indications for Use Form – WTVx/9-3 Transducer

System:	SonoSite Maxx™ Series Ultrasound System						
Transducer:	WTVx/9-3 MHz Transducer						
Intended Use:	Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:						
Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Spec.)	Other (Spec.)
Ophthalmic							
Fetal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Abdominal							
Intra-operative (Abdominal organs and vascular)							
Intra-operative (Neuro.)							
Laparoscopic							
Pediatric							
Small Organ (breast, thyroid, testicles, prostate)							
Neonatal Cephalic							
Adult Cephalic							
Trans-rectal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Trans-vaginal	N	N	N	N	N	B+M; B+PWD; B+CD; B+CWD	Note 1
Trans-urethral							
Trans-esoph. (non-Card.)							
Musculo-skel. (Convent.)							
Musculo-skel. (Superfic.)							
Intra-luminal							
Other (spec.)							
Cardiac Adult							
Cardiac Pediatric							
Trans-esophageal (card.)							
Other (spec.)							
Peripheral vessel							
Other (spec.)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:

Note 1: Other includes color power Doppler, combined B and color power Doppler, 3-D/4-D imaging, tissue harmonic imaging, SonoRes/SonoHD imaging, SonoMB compound imaging, tissue Doppler imaging (TDI), elastography imaging, strain rate imaging, imaging for guidance of biopsy and imaging to assist in the placement of needles and catheters in vascular or other anatomical structures. Color Doppler includes velocity color Doppler. Color Doppler can be combined with any imaging mode. M-Mode includes anatomical M-Mode, and color M-Mode.

Prescription Use (Per 21 CFR 801.109)

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